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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,360	07/30/2001	Leroy E. Hood	P-IS 4627	2535
41552	7590	05/12/2006	EXAMINER	
MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/919,360

Applicant(s)

HOOD ET AL.

Examiner

Shubo (Joe) Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 8-16, 30-32, 36-46 and 48-83 is/are pending in the application.  
4a) Of the above claim(s) 3 and 45 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-4, 8-16, 30-32, 36-44, 46, 48-55 and 74-83 is/are rejected.  
7) ☒ Claim(s) 56-73 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/19/05, 2/27/06.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' amendment and request for reconsideration in the communication filed on 2/23/06 are acknowledged and the amendment entered.

Applicant's arguments in response to the previous Office action have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous Office actions are hereby withdrawn. The following rejections and/or objections are reiterated from the previous Office action, and constitute the complete set presently being applied to the instant application.

#### ***Withdrawn Rejections***

The rejection of claims 57-64, 66-73, and 75-82 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) is hereby withdrawn in view of applicants argument (pages 10-11 of the response filed 2/23/06).

#### ***Claim Rejections-35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-32, 36-43, 55, and 74-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the phrase “substantially similar response” recited in claim 30 and its dependent claims are not clear. The terms “substantially” and “similar” are relative terms, which render the claims indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. While both terms may be definite in certain situations where guidelines are provided in the specification for ascertaining the scope of the claimed invention (see MPEP 2173.05(b)), in the instant case, the specification does not provide any guideline as to the standard for being “similar” and “substantially similar.” Since the responses by different individuals to a particular drug could be vastly different, both qualitatively and quantitatively, without a clear and definitive guideline in the specification, one of ordinary skill in the art would not be reasonably clear what responses fall into the scope of being “similar” or “substantially similar.”

This rejection is reiterated from the previous Office action. Applicants’ argument filed 2/23/06 has been fully considered but not found persuasive. Applicants argue that the specification disclose that substantially similar response to a drug can refer to a substantially similar expression profile, etc. (page 43 of the specification). This is not found persuasive because while the specification gives examples for a “substantially similar response” to a drug, it does not provide an explicit definition, nor provide any guideline as to the standard for being “similar” and “substantially similar.” Furthermore, even for the example given, when “substantially similar response” to a drug refers to a “substantially similar expression profile,” without a clear and definitive guideline in the specification for ascertaining “similar” or “substantially similar” expression profile, qualitatively and quantitatively, one of ordinary skill in the art still would not be reasonably clear what profiles fall into the scope of being “similar” or “substantially similar,” and hence would not be reasonably clear as to what responses fall into the scope of being “similar” or “substantially similar.”

Claims 31-32, 36-43, 55, and 74-82 are rejected for being dependent from claim 30 and thus comprising the indefinite limitation.

***Claim Rejections-35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4, 8-16, 30-32, 36-44, and 46, 48-55 and 83 are rejected under 35 U.S.C. 102 (e)(2) as being clearly anticipated by Friend et al. (P/N 6,218,122).

In the title and abstract, Friend et al. summarizes the monitoring of cellular constituents in connection with therapies. The drug therapy practice perturbs the systems of an individual and thus perturbation response profiles are produced in the disclosure of Friend et al. Figures 1 - 3 depict various multidimensional coordinate point response profiles as in the instant claim limitations. The DETAILED DESCRIPTION section of the reference in column 4, line 46, through column 29, line 39, goes on at length and in detail for such response profile production and analysis. This is also the subject matter of the instant claims with a specific classification of a group of individuals into a drug response population regarding disease states being treated. See, for example, column 6, line 48, through column 8, line 62. Cellular constituents being measured for such profiles include RNA (nucleic acid) and protein expression as set forth, for example, in column 2, lines 38-47, as also required in the instant claims 11-13, 39-41, and 50-52. The elected

specie of the beneficial drug response for alleviating a sign or symptom associated with a disease as in instant claim 4 is also set forth in the reference in column 8, lines 35-39. The basic classification of a population by drug responsiveness as instantly claimed is set forth in the reference in column 9, lines 2-14 and lines 39-47, as monitoring subjects as to efficacy of a drug therapy in a clinical trial. Various molecules may be monitored regarding expression profiles, such as small molecules (instant claims 15, 43, and 54) like glucose as set forth in the reference in column 12, lines 34-41, or antibodies (instant claims 14, 42, and 53) as in the reference in column 12, lines 62-65. An array as a target for cellular measurements is disclosed in column 20, lines 55-59, as in instant claim 10. Leukocyte specimen measurements (as in instant claim 16) are disclosed in the reference via the white blood cell profiling set forth in column 12, lines 31-41.

This rejection is reiterated from the previous Office action mailed 11/17/04 and maintained for reasons of record.

Applicants' argument filed 2/23/06 has been fully considered but not found persuasive. The argument is on the ground that Friend et al. does not teach the same method as claimed in the instant invention because it does not disclose creating a multidimensional space of  $n$  dimensions, wherein the space contains  $n$  axes and each of the axes relates to the expression level of a molecule of the  $n$  molecules. This is not deemed persuasive mainly because the limitation "each of the axes relates to the expression level of a molecule of the  $n$  molecules" is broad due to the use of the term "relates to." Figure 1 of Friends et al. clearly depicts a 2-dimensional space, and 2 is the number of the different types of molecules analyzed, i.e. two different copies of the diploid SUN2 gene: the mutant and the wild type. Furthermore, there are

two axes in Fig. 1, and each of them, “intensity” and “expression ratio,” is related to expression level of the molecules analyzed.

### ***Claim Objections***

Claims 56-73 are objected to as being dependent from rejected claims 1, 16 or 30.

Appropriate correction is required.

### ***Conclusion***

No claim is allowed.

### **THIS ACTION IS MADE FINAL.**


Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136

(a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

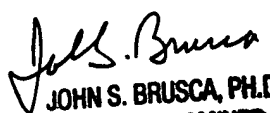
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can

be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D. 

Patent Examiner

 10 May 2006  
JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER